TABLE IV

Log Rank Tests to Compare Survival

Index Score	Log Rank Test P Value
≥-5 vs. < -6	$p<0.0001$
≥-6 vs. < -7	$p<0.0007$
≥-7 vs. < -8	$p<0.0548$

These results are shown graphically in Figure 3 in a retrospective analysis of 40 breast cancer patients having a summed prognostic (risk) index score greater than -5 (GE -5) or less than -6 (LE -6). In this study, survival was correlated with risk index scores greater than or equal to -5 (about 80% survival at 60 months post-diagnosis) *versus* about 20% survival for patient having tumors with index scores less than -6.

These results were also analyzed using multivariate analysis including angiogenesis, tumor size and lymph node status. These results showed that the index was more predictive of patients' prognosis for survival than the commonly-used indices of tumor size or lymph node status.

These results demonstrate that the tumor progression index is a statistically reliable predictor of tumor prognosis and disease progression for breast cancer.

EXAMPLE 3

Tumor Progression/Prognosis Analysis for Prostate Cancer

The immunohistochemical analyses described above in Example 1 were applied to prostate cancer samples. In addition, androgen receptor expression was assayed for these tumors, due to the recognized correlation between androgen receptor expression and poor prognosis/survival in these patients.

In this study, 104 prostate cancer patient tumor samples were assayed for nuclear accumulation of p53, TSP-1 expression, androgen receptor (AR) gene expression and microvascularization. These assays were performed immunohistochemically as described above

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in Example 1, except that androgen receptor expression was determined using an anti-AR antibody (Biogenics, used at 1:20 dilutions).

The results of these studies closely paralleled the results obtained with breast carcinoma, and the indices derived from the p53, TSP-1 and angiogenesis/microvascularization data were identical to those shown in Table III. In addition, AR expression was found to be negatively correlated with prognosis and survival using multivariate analysis (Cox regression analysis), which showed statistical significance ($p=0.0077$). Interestingly, the presence of nuclear accumulation of p53 was correlated with AR expression ($p<0.0041$).

The risk index incorporating levels of nuclear p53, TSP-1 expression and angiogenesis was found to be significantly associated with survival. Survival in patients with a risk index of -8 or less was significantly lower than that in patients with a prognostic (risk) index of -7 or greater ($p<0.0001$). The risk index was also associated with survival ($p<0.0061$) even after adjustment for age and stage.

These results are shown graphically in Figure 4. This Figure illustrates the results of a retrospective analysis of 104 prostate cancer patients having a summed prognostic (risk) index score greater than -7 (GE -7) or less than -8 (LE -8). In this study, survival was correlated with risk index scores greater than or equal to -7 (about 95 months to 20% survival post-diagnosis) *versus* about 30 months to 20% survival post-diagnosis for patients having tumors with index scores less than -8. These results demonstrated that the prognosis (risk) index was reliable for predicting poor prognosis/increased disease progression based on the tested tumor markers.

It should be understood that the foregoing disclosure emphasizes certain specific embodiments of the invention and that all modifications or alternatives equivalent thereto are within the spirit and scope of the invention as set forth in the appended claims.

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